

## INTRODUCTION

The new Laboratory Manual (LM) is a significant update and revision of the August 29, 1989 Laboratory Procedures Manual. The LM is expanded to include laboratory quality objectives for ISO 17025 accreditation, additional training modules, and new sections to address measurement traceability, statistics, analysts on inspection, environmental health and safety. Two volumes are dedicated to historical guidance documents and useful websites for master lists of laboratory Quality Management Systems. The Laboratory Manual source document is stored electronically and is accessed through three websites. The primary access route is through the Division of Field Science website <http://web.ora.fda.gov/dfs/policies/manuals/> which contains Volumes I, II, III, and V. Each entry in the DFS Lab Manual "Table of Contents" is directly linked to that portion of the manual. Orientation and Training, Volume IV, resides on the ORA U website at <http://web.ora.fda.gov/dhrd/LabManual/default.htm>.

Limited hardcopy printing of the Laboratory Manual and distribution is made only to the ORA field laboratories and to the National Technical Information Service (NTIS) for non-government distribution. Hardcopy printings of the Laboratory Manual have a statement indicating "uncontrolled copy" as of the printing date. New updates to the manual are accomplished electronically through a review/approval process and posted at the websites mentioned previously.

The Laboratory Manual provides a central authoritative source for the approved and mandatory laboratory procedures, policies, fitness-for-use-criteria, and quality assurance practices to be used by ORA scientists in the course of their daily regulatory work. This manual is the result of a cooperative effort between the field laboratory staff and headquarters personnel. The editors are as follows:

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Suggestions and comments for improvement may be sent to the attention of Darryl Brown, Chief Editor, ([dbrown5@ora.fda.gov](mailto:dbrown5@ora.fda.gov)) for inclusion in the manual.

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